

DOCKET NO.: DEY-0002
PATENT APPLICATION

SERIAL NO.: 09/257,902
FILED: FEBRUARY 25, 1999

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ingestion is effective to prevent iron deficiency anemia, said composition comprising a therapeutically effective amount of microencapsulated iron granules in combination with a lipid-based excipient, where the packaging material additionally indicates that the composition is to be added to a semi-solid food, pureed food or liquid food.

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30 (Amended). An article of manufacturer as defined in claim 12, wherein said therapeutically effective amount of micro-encapsulated iron is in the range of about 40-80 mg.

REMARKS

Status of the claims

Claims 7-31 are in the application.

By way of this amendment, claim 31 has been canceled and claims 7, 12, 28 and 30 have been amended.

Upon entry of this amendment, claims 7-30 will be pending.

Summary of the Amendment

Claim 7 has been amended to more clearly define the invention. As amended, claim 7 indicates that the food is administered directly after addition of the therapeutic composition to it

and without further preparation. Support for this amendment is found throughout the specification such as on page 3, lines 12-13. No new matter has been added.

Claim 12 has been amended to more clearly define the invention. As amended, claim 12 recites that the composition comprises a therapeutically effective amount of an admixture of microencapsulated iron granules in combination with a lipid-based excipient. Support for this amendment is found throughout the specification such as on page 4, line 32 to page 5, line 1. No new matter has been added.

Claim 28 has been amended to be in independent form. No new matter has been added.

Claim 30 has been amended to correct an obvious typographical error. No new matter has been added.

Response to the Official Action

Applicants note that the office action summary indicates some claims have been allowed while the detailed action indicates different claims have been rejected for that listed on the office action summary. Clarification is respectfully requested.

Claims have been rejected as obvious over Kovacs. Kovacs discloses addition of an iron-containing composition to breakfast cereal followed by further processing such that the iron composition becomes part of the cereal.

The present invention relates to an iron supplement and method of using the same which

comprises an admixture of microencapsulated iron granules and a lipid excipient. The admixture is packaged. The admixture may be removed from the package and added to food which can then be administered without further processing.

Accordingly, while Kovacs teaches further processing of the food product following addition of the iron supplement and prior to administration to the consumer, the present invention specifically claims the direct administration to the consumer following addition of the supplement without further processing. Kovacs neither teaches nor suggests the claimed invention.

Further, Kovacs teaches a breakfast cereal which has been processed to contain iron supplement. The cereal is heated to incorporate the iron supplement to it.

The present invention claims articles of manufacture which comprise an admixture of microencapsulated iron granules and lipid excipient. Kovacs does not teach or suggest such articles of manufacture since Kovacs teaches processing the cereal. Kovacs does not teach or suggest articles of manufacture which comprise an admixture of microencapsulated iron granules and lipid excipient.

Claim 30 was rejected for a misspelled word, manufacturer. As amended, claim 30 is clear and definite.

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Conclusion

Reconsideration and allowance of this application is now respectfully requested. For the foregoing reasons, Applicants respectfully request that claims 7-30 be allowed at this time.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Respectfully submitted,



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Date: September 4, 2001

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 31 has been canceled.

Claims 7, 12, 28 and 30 have been amended as follows:

7 (Twice Amended). A method for preventing iron deficiency anemia in a mammal comprising the steps of:

- a) removing a composition comprising micro-encapsulated iron granules and a lipid-based excipient from packaging material;
- b) adding a therapeutically effective amount of said composition to a food; and
- c) administering the food to said mammal directly after adding said composition to said food without further preparation.

12 (Amended). An article of manufacture comprising packaging material and a pharmaceutical composition contained within said packaging material, wherein said pharmaceutical composition is therapeutically effective to prevent iron deficiency anemia, and wherein the packaging material comprises a label which indicates that the composition comprises iron and that iron ingestion is effective to prevent iron deficiency anemia, said composition comprising a therapeutically effective amount of an admixture of microencapsulated iron granules in combination with a lipid-based excipient

28 (Amended). An article of manufacture comprising packaging material and a pharmaceutical composition contained within said packaging material, wherein said pharmaceutical composition is therapeutically effective to prevent iron deficiency anemia, and

wherein the packaging material indicates that the composition comprises iron and that iron ingestion is effective to prevent iron deficiency anemia, said composition comprising a therapeutically effective amount of microencapsulated iron granules in combination with a lipid-based excipient, where the packaging material additionally indicates that the composition [as defined in claim 12, where the label additionally indicates that said composition] is to be added to a semi-solid food, pureed food or liquid food.

30 (Amended). An article of [manufactuer] manufacturer as defined in claim 12, wherein said therapeutically effective amount of micro-encapsulated iron is in the range of about 40-80 mg.